R E M A R K S

Claims 1-31 have been cancelled without prejudice or disclaimer of the subject matter therein and claims 32-62 respectively are presented to present said claims in accordance with USA practice under 35 USC 112, and to eliminate multiple-dependent form claims.

No multiple-dependent claim fees should apply in this application.

The specification has been amended for formal improvement to comply with USA practice.

An Abstract is presented on a separate page.

Attached hereto is a marked-up version of the changes made to the specification by the current amendment. The attached pages are captioned **"Version with markings to show changes made"**

The Examiner is respectfully requested to enter this Preliminary Amendment prior to calculation of the filing fee as of the national stage filing date, and to provide an action on the merits.

Respectfully submitted
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USA PCT National Stage Patent Application
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Albert Louis Victor Jozef Claessens
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MOULDING SUITABLE FOR PHARMACEUTICAL APPLICATIONS
AND METHOD FOR PRODUCTION THEREOF

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION

Page 2, please replace the paragraph beginning at line 6 with the following rewritten paragraph:

With regard to the moulding, the object is achieved [firstly and] substantially [by the respective subject matter of Claims 1 and 2, it firstly being of significance, Claim 1, in addition to the features already specified, that] wherein the moulding consists, at least in a subregion, of a thermoplastic elastomer material with a mineral filler content of 30% or more and this subregion has a hot-runner injection point which is formed as a smooth-surfaced mark. The object is also achieved wherein [In addition, Claim 2,] it is also of significance that, in the case of a second part of the moulding, the latter consists of a different plastics, for example a conventional injection-moulding plastics, such as PP, PE or the like, which is then used to inject over the injection point of the first subregion. In such a case, the injection point of the subregion formed from the flexible elastomer material in particular can then also be formed as a hot-runner injection point, which is then, again preferably, also formed as a smooth-surfaced mark. According to the invention, it has been recognized that a thermoplastic elastomer material with

a mineral filler content of 30% or more is suitable for meeting the material requirements of pharmaceutical mouldings of this type. This is so at least when, in the case of outward exposure on the moulding, the injection point is formed by a hot-runner injection point and a smooth-surfaced mark is created. Disturbing streaking or instances of material unevenness, in particular in the region of the injection point, can no longer be found. Nevertheless, such a moulding can be efficiently produced by customary injection-moulding processes, but with hot-runner injection. It is preferable in this context that the mark which is created on the moulding by the hot-runner injection point goes over into the moulding wall surrounding it without being offset outwards. In particular, it is preferred for the smooth-surfaced mark to go over into the moulding wall surrounding it in a co-planar manner. Furthermore, however, it may also be recommendable in special cases for the mark to be raised with respect to the moulding wall surrounding it, that is to say it is offset outwards. This is so for example if, as is the aim also [of Claim 2] explained above, the two-component injection-moulding process is being used or the moulding consisting of the elastomer material is part of a multi-part article, in which the injection point is covered by a further part or is even encapsulated therein. This is so because a raised mark may also be recommendable for positive engagement in a further part.

Page 6, please replace the paragraph beginning at line 27 with the following rewritten paragraph:

A further article which may be embodied by such a moulding serving for pharmaceutical uses is a sealing element, as used in the case of so-called "bottle-pack" bottles. In this respect, reference is made in particular to the disclosure of German Patent Applications 195 00 460 and 196 20 196, the contents of which are hereby also incorporated in full, also for the purpose of including features of these prior publications in claims of the present patent application. Such a sealing element customarily has a peripheral flange of a smaller wall thickness or, on the upper side and/or underside, a peripheral groove associated with the edge and a central region of greater wall thickness. Here, too, the injection preferably takes place centrally in the upper outer surface. Moreover, the geometrical features described also apply here, for instance with regard to the thickness of the walls, and the features regarding the purity and freedom from streaks, as already explained before with respect to the moulding in general and the other uses. In particular, such an article may also be produced in the multi-component injection-moulding process, the one subregion, for instance the subregion of rigid plastics forming the outer cap, then forming the mould (again at least partially) for the subsequently injected elastomer-material subregion. It is also possible, however, to adopt the reverse procedure. In particular in the latter case, it is possible, and may even be appropriate, to produce the hot-runner injection point in such a way that it is raised with respect to the surrounding moulding wall of elastomer material, but in the end depressed with respect to the moulding wall of a second subregion of another plastics component, in particular a rigid plastics component.

Page 8, please replace the paragraph beginning at line 28 with the following rewritten paragraphs:

When forming a protective cap for medical syringes in the plastic injection-moulding process specified above, a solid cap hat and a comparatively thin-walled cap neck [is] <u>are</u> moulded. In an advantageous way, the hot-runner injection takes place centrally on the cap hat. Otherwise, from a production engineering viewpoint, the same features as also already described above with respect to the production of the stopper or the seal are preferred.

BRIEF DESCRIPTION OF THE DRAWINGS

Page 11, please replace the paragraph beginning at line 8 with the following rewritten paragraph:

The stopper 1 takes the form of a hollow stopper. The latter fits in a sealing manner in a substantially cylindrical mouth 10 of the neck 4. The cavity of the hollow stopper [9]<u>1</u>, opening towards the space inside the bottle, has the reference numeral 11.

Page 14, please replace the paragraph beginning at line 14 with the following rewritten paragraph:

The injection point A (cf. for instance Figures 6 and 13) of the hot-runner injection is denoted on the moulding (cf. for example Figures 2, 4, 7, 8, 14) by 24. It may lie centrally on the protective cap 2 and preferably lies centrally on the stopper 1, as also in the case of the seals 44. This achieves the effect of a uniform distribution at high flow rate. Aesthetic defects do not occur. There are not even any visual irregularities such as colour deviations. Furthermore, customary injection moulds can be used. In this case, the cavity filling is largely temperature-independent. It can be between 200 and 280°C, without any major differences in quality being evident.

Page 16, please replace the paragraph beginning at line 5 with the following rewritten paragraph:

With respect to the mouldings described, the list of requirements in terms of the material also take into account that such mouldings should be autoclave-resistant. They withstand temperatures of 120°C over a relatively long period of time. In spite of the admixture explained, the material remains outstandingly suitable for injection moulding. The required compromise has been found. Moreover, plasticizer is also added to the thermoplastic elastomer material.

Page 17, please replace the paragraph beginning at line 26, with the following rewritten paragraph:

In the case of the embodiment of Figure 14, the article according to Figure 11 is produced in the two-component injection-moulding process, the injection point 24 being formed such that it is offset outwards with respect to the surrounding moulding wall, in a way corresponding to a mould-related design according to Figure 13. Following the moulding of elastomer material formed here as a seal 44, the surrounding cap [44] 43 has been moulded, including a cap part formed here as projecting portion 51 and extending over the injection point 24. The feature that, when produced in the two-component injection-moulding process, the injection point 24 of the subregion of the (overall) moulding, which consists of thermoplastic elastomer material, has the further subregion of the moulding of plastics of the second component extending over it is also significant, irrespective of how the injection point 24 is formed.